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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,422	11/02/2001	Paul Polakis		7194

7590 02/27/2003

ONYX Pharmaceuticals, Inc.
3031 Research Drive
Richmond, CA 94806

EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/053,422	Polakis et al.
Examiner	**Art Unit**
Shin-Lin Chen	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-11 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4 and 5, drawn to isolated beta-catenin protein, and a protein complex containing beta-catenin and a transcription factor, classified in class 530, subclass 350.

II. Claims 2 and 3, drawn to isolated DNA encoding beta-catenin protein, classified in class 536, subclass 23.5.

III. Claims 6-8, drawn to a method of diagnosing for disease, such as cancer, by determining the presence of beta-catenin DNA, classified in class 435, subclass 6.

IV. Claims 6-8, drawn to a method of diagnosing for disease, such as cancer, by determining the presence of beta-catenin protein, classified in class 435, subclass 7.1.

V. Claims 9-11, drawn to a method of identifying compounds that inhibits unwanted cell growth comprising assaying for compounds that prevent formation of beta-catenin and transcription factor complex, classified in class 435, subclass 4.

Claims 6-8 link(s) inventions III-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 6-8. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct from each other because they are drawn to different composition having different chemical structures, physical properties, and biological functions: protein vs DNA. Search for protein does not require search for DNA and vice versa. They have different classifications and the search would not be coextensive. Thus, groups I and II are patentably distinct.

Groups III and IV are distinct from each other because they are drawn to materially different methods that uses different composition having different chemical structures, physical properties, and biological functions: nucleic acid to detect DNA and antibody to detect protein. Those methods differ at least in method steps, reagents and doses used, schedule used, response variables, and criteria of success. They have different classifications and require separate search. Thus, groups III and IV are patentably distinct from each other.

Groups III-IV and group V are distinct from each other because they are drawn to materially different methods that differ at least in objectives, method steps, reagents and doses used, schedule used, response variables, and criteria of success. Diagnosing a disease is different from identifying compounds that prevent the formation of a complex containing beta-catenin and

a transcription factor. They have different classifications and require separate search. Thus, groups III-IV and group V are patentably distinct from each other.

Groups I-II are distinct from groups III-V. Groups I-II and groups III-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.E.P.. § 806.05(h)). In the instant case the isolated DNA can be used for producing a recombinant polypeptide. The isolated protein can be used to produce antibody and can be used for protein binding assay. Thus, groups I-II are patentably distinct from groups III-V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D. S Chen

We claim:

1. Isolated substantially purified stabilized beta-catenin protein, or fragments thereof.

2. Isolated DNA that encodes substantially purified stabilized beta-catenin protein, or fragments thereof.

3. Isolated DNA that encodes substantially purified stabilized beta-catenin protein, or fragments thereof, wherein said isolated DNA is cDNA.

4. An isolated substantially purified protein complex comprising purified stabilized beta-catenin protein, or fragments thereof, and a transcription factor.

5. An isolated substantially purified protein complex as described in claim 4, wherein said transcription factor is a member of the Lef/Tcf family.

6. A method of diagnosing for disease based on unwanted cell growth comprising determining the presence of stabilized beta-catenin in said cells.

7. A method as described in claim 6 wherein said disease is cancer.

8. A method as described in claim 6 wherein said cancer is melanoma.

9. A method of identifying compounds that inhibit unwanted cell growth comprising assaying for compounds that prevent the formation of a complex comprising beta-catenin and a transcription factor.

10. A method of identifying compounds that inhibit unwanted cell growth as described in claim 9 wherein said transcription factor is a member of the Lef/Tcf family.

11. A method of identifying compounds that inhibit unwanted cell growth as described in claim 10 wherein said transcription factor is Lef.

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